Către Agenţia Medicamentului şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. ..... din .....

Solicitantul **Dita Estfarm SRL**, cu sediul **str-la Burebistra 23, MD-2032, Chisinau, Republica Moldova**, tel./fax: **022 782 875**, e-mail: **irina.sandu@dita.md** solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a producătorului **Taizhou Kangjian Medical Equipment Co., Ltd., China:**

- Periuță citologică

Se anexează următoarele acte:

- Actul de reprezentanță între producător și reprezentantul autorizat în Republica Moldova;
- Declarația de conformitate CE;
- Certificat de conformitate CE;
- Declarația pe propria răspundere a solicitantului;
- Lista dispozitivelor medicale (format Excel).

Data **14.09.2023** Semnătura _____

Tabelul de recepționare a notificării
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Digitally signed by Moraru Grigore
Date: 2023.09.17 11:02:08 EEST
Reason: MoldSign Signature
Location: Moldova

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: **Dita Estfarm SRL**, cu sediul **str-la Burebistra 23, MD-2032, Chisinau, Republica Moldova**,

declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivelor medicale ale producatorului **Taizhou Kangjian Medical Equipment Co., Ltd., China:**

- Periuță citologică

Sunt autentice și corespund realității.

Numele, prenumele şi funcţia:

RA-Manager – Sandu Irina

Semnătura _____

Data ***14.09.2023***

台州康健医用器械有限公司

TAIZHOU KANGJIAN MEDICAL EQUIPMENT CO.，LTD

浙江省玉环市机电工业园区

ADD:THE MACHINE ELECTRICITY ZONE OF YUHUAN CITY

ZHEJIANG PROVINCE 317600，P.R.CHINA

TEL:0086-576-87225930 FAX:0086-576-87239885

We, **TAIZHOU KANGJIAN MEDICAL EQUIPMENT CO.，LTD**

based in _**THE MACHINE ELECTRICITY ZONE OF YUHUAN CITY,ZHEJIANG PROVINCE 317600，P.R.CHINA.**

assign Dita Estfarm LLC, based in No.23 Burebista street, Chisinau MD -2032, Republic of Moldova, as **authorized representative** in correspondence with the conditions of Regulation (EU) 93/42.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Place:TAIZHOU,CHINA

Date: 11-SEP-2023

Signed:

台州康健医用器械有限公司
TAIZHOU KANGJIAN MEDICAL EQUIPMENT CO.,LTD

TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60156376 0001

Report No.: 15085363 008

Manufacturer:
Taizhou Kangjian Medical
Equipments Co., Ltd.
The Machine Electricity Zone
(Hang Ni Kan) of Yuhuan County
Zhejiang Province 317600
P.R. China

Products: Medical Devices

(see attachment for products and additional site included)

Replaces Approval, Registration No.: DD 60147806 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Fuxiu Sheng

Effective Date: 2021-04-28

Date: 2021-04-28

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60156376 0001
Report No.: 15085363 008

Manufacturer:
Taizhou Kangjian Medical Equipments Co., Ltd.
The Machine Electricity Zone (Hang Ni Kan) of Yuhuan County
Zhejiang Province 317600
P.R. China

Products:

Disposable Cervical Brushes, Disposable Cervical Spatulas, Disposable Cervical Cell Sampling Spoons, Disposable Gynecological Sets, Oxygen Masks, Non Rebreathing Masks, Nebulizer Masks, Venturi Masks, Nebulizer with Mouthpieces, Nasal Oxygen Cannulae;

Aspects of manufacture concerned with securing and maintaining sterile conditions:

Sterile Vaginal Speculums for Single Use, Disposable Anoscopes, Disposable Nasal Speculums, Disposable Tongue Depressors, Plastic Forceps

Site included:

Qiaotian Community (Tiantong Road West) of Tongcheng Town, Tianchang City, Anhui Province 239311, China

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Fuxiu Sheng

Date: 2021-04-28

Business Stream Products
Certification Department

TÜVRheinland®
Precisely Right.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Taizhou Kangjian Medical
Equipments Co., Ltd.
The Machine Electricity Zone
(Hang Ni Kan) of Yuhuan County
ZHEJIANG PROVINCE 317600
P.R. CHINA

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date April 30, 2021

S.R.L. "DITA ESTFARM" IDNO 1002600046359 SOCIETATEA CU RĂSPUNDERE LIMITATĂ, REPUBLICA MOLDOVA, mun. CHIȘINĂU 18

Application for : QMS Produktion, Anhang V MDD
Certificate No. : DD 60156376 Sheet 0001
Device : Only for QM-System audit
Test requirement : Richtlinie 93/42/EWG

Dear Madame or Sir,

Enclosed please find the new certificate No. DD 60156376 0001 replacing the previous certificate.

With effective date of the new certificate, the previous certificate (number see new certificate) becomes invalid.

Kind regards

Certification body

Fuxiu Sheng

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

Tillystraße 2
90431 Nürnberg

Tel. +49 911 655-5225
Fax +49 911 655-5226
Mail service@de.tuv.com
Web www.tuv.com/safety

台州康健医用器械有限公司
Taizhou Kangjian Medical Equipment Co., Ltd.

EC DECLARATION OF CONFORMITY

Document number: TKY/CE-TD-CS-18

Name and address of the manufacturer:	Taizhou Kangjian Medical Equipment Co., Ltd. Address: The machine electricity zone (Hang Ni Kan) of Yuhuan county, Zhejiang province317600, China Branch company address: Qiatian Community (Tiantong Road West) of Tongcheng Town, Tianchang City, Anhui Province 239311, China

We declare under our sole responsibility that

the medical device:	**Disposable Gynecological Collectors** Modle: disposable cervical brush, disposable cervical spatula and disposable cervical cell sampling spoon.
of class:	IIa Sterile medical devices

According to MDD 93/42/EEC Annex Ⅸ Rule 6, the Gynecological Collectors belong to class IIa Sterile medical devices.

Meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device.

Conformity assessment procedure: **Directive 93/42/EEC Annex v**

Registration No.: DD 60156376 0001

Notified Body:

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Deutschland
CE 0197

Yuhuan, 2021-09-10

Place, date

Xiong Tao

Name and function

台州康健医用器械有限公司
TAIZHOU KANGJIAN MEDICAL EQUIPMENTS CO.,LTD.

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
1		Periuță citologică